UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,624	10/04/2001	Wesley B. Bruce	1263	1396

27310 7590 10/17/2002

PIONEER HI-BRED INTERNATIONAL INC.
7100 N.W. 62ND AVENUE
P.O. BOX 1000
JOHNSTON, IA 50131

EXAMINER
MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 10/17/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/970,624	BRUCE, WESLEY B.	
	Examiner	Art Unit	
	Ashwin Mehta	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-9 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that the polynucleotide of Group I can be used to produce the polypeptide of Group II using the method of Group I, and as such claim 8 is directed to this process and may be considered a unifying claim. This is not found persuasive because the isolated protein of group II can be produced by means that do not require the polynucleotide or method of Group, for example chemical synthesis. Applicant also argues that the inventions of Groups I and II have the same function: to modulate the level of nitrate responsive root transcriptional factor. However, the specification does not teach that the nitrate responsive transcription factor modulates itself. Applicants also argue that Groups I and II are sufficiently closely related to each other so as to be searched and examined together without undue burden on the Examiner. However, a search for the isolated protein of Group II would not necessarily reveal anything about the polynucleotide and method of Group I.

The requirement is still deemed proper and is therefore made FINAL. Non-elected claim 10 is withdrawn from consideration, and requires cancellation.

Specification

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, for example at page 15, line 10 and page 64, line 18. Applicant

is required to delete these and any other embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

3. The specification is objected to for the presence of blank lines on page 20, line 30 and page 21, line 22.

4. The specification fails to comply with the sequence rules of 37 CFR 1.821-1.825. A nucleotide sequence appears on page 64, lines 6-7, which should be part of the sequence listing and identified with a sequence identifier.

Claim Objections

5. Claims 2, 4 and 8 are objected to for the following minor informalities:

In claim 2, line 1, the article "a" before "member" should be --the--.

In claim 4: the article "a" before "recombinant" should be --the--.

In claim 8: the article "a" should appear in line 1 before "nitrate-responsive."

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 1-9 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

The claims are broadly drawn towards any isolated nucleic acid comprising a member selected from the group consisting of any polynucleotide (a) having at least 75% sequence identity to SEQ ID NO: 1, as determined by the GAP algorithm, (b) encoding SEQ ID NO: 2, (c) amplified from any nucleic acid library using primers that selectively hybridize within SEQ ID NO: 1 under any hybridization condition, (d) which selectively hybridizes to SEQ ID NO: 1 under any hybridization condition and a wash in 01.X SSC at about 60° to 65°C, (e) SEQ ID NO: 1, (f) which is complementary to (a), (b), (c), or (e), and (g) comprising at least any 50 contiguous nucleotides from a polynucleotide of (a), (b), (c), (d), (e), or (f); a recombinant expression cassette comprising said member operably linked in sense or antisense orientation to a promoter; any host cell or transgenic plant comprising said expression cassette; any transgenic seed from said plant; a method of modulating the level of nitrate-responsive root transcriptional factor in a plant, comprising introducing into a plant cell any recombinant expression cassette comprising said polynucleotide operably linked to a promoter, regenerating a plant, and inducing expression of said polynucleotide; or wherein the plant of said method is maize.

The specification indicates that a polynucleotide of the present invention is inclusive of a polynucleotide encoding a polypeptide of SEQ ID NO: 2, including the polynucleotide of SEQ ID NO: 1 (page 21, lines 5-6). The specification indicates that manipulation of a nitrate-responsive gene such as the Arabidopsis ANR1 in agronomic crops could be of value in maximizing plant utilization of available nitrogen and in reducing agricultural nitrogen inputs, providing economic and environmental benefits (page 3, lines 4-6). The specification also indicates that the object of the present invention is to provide nucleic acids and proteins relating to a root transcriptional factor and to provide transgenic plants comprising the nucleic acids and

methods for modulating, in a transgenic plant, the expression of the nucleic acids (page 3, lines 16-20).

The utility guidelines require disclosure of at least one specific, substantial, and credible utility for an invention, or for the invention to have a well-established utility that is specific, substantial, and credible. It is not clear that the specification teaches a specific and substantial use of the invention. The specification discusses that the Arabidopsis ANR1 gene is nitrate-inducible and encodes a MADS-box transcription factor that is a component of a signal transduction pathway that links external nitrate to increased lateral root proliferation and that manipulation of nitrate-responsive genes such as ANR1 in agronomic crops could be of value in maximizing plant utilization of available nitrogen and in reducing agricultural nitrogen inputs, that improved control of lateral root proliferation could have useful applications in soil remediation, that increased root biomass may be beneficial in production of specific structural carbohydrates, and that manipulation of nitrate-responsive genes could also be useful in stimulating root proliferation of cuttings for plant propagation (page 2, line 17 to page 3, line 13). However, the specification does not actually teach that the amino acid sequence of SEQ ID NO: 2 is a nitrate-responsive root transcription factor, nor does it teach how it relates to a root transcription factor. The specification does not assert the function of SEQ ID NOs: 1 or 2 at all. The discussion of ANR1 appears to be the only apparent connection with any nitrate-responsive transcription factor. The specification does not actually teach the function of SEQ ID NOs: 1 and 2, and it appears as if one is to assume that SEQ ID NO: 2 is a nitrate-responsive transcription factor. The specification does not provide any data at all as to why SEQ ID NO: 1 is considered to encode a nitrate-responsive root transcription factor. Nor does the specification

teach the genes whose expression would be affected SEQ ID NO: 1, and whose expression would be required to improve the control of lateral root proliferation. The only place that the specification even mentions SEQ ID NOs: 1 and 2 is on page 21, and no discussion is present teaching the function or identities of these sequences. It appears then that further basic research is required to determine the functional properties of SEQ ID NO: 2 and to determine the identities of the genes that it controls.

Further, SEQ ID NO: 1 shares less than 19% sequence identity with ANR1, and 86.7% identity with the coding region of ZmMADS2, which encodes a MADS box transcription factor that is expressed in pollen and pollen tubes. The ZmMADS2 amino acid sequence shares 100% identity with instant SEQ ID NO: 2 (Heuer et al., 2000, Sex. Plant Reprod., Vol. 13, pages 21-27; GenBank Accession Nos. AF112149 and AAG09919). Given the low level of identity of SEQ ID NO: 1 with ANR1 and the 100% identity of instant SEQ ID NO: 2 with a pollen-expressed transcription factor, it does not appear that SEQ ID NO: 1 encodes a nitrate-responsive root transcription factor. As the function of SEQ ID NOs: 1 and 2 is not described, the utilities of the claimed transgenic plants and method are not clear, either. While expressing the claimed nucleotide sequences in plants is interesting from a basic science standpoint, since the specification does not teach the function or identity of SEQ ID NOs: 1 and 2, further basic research is required to determine if SEQ ID NO: 2 functions as a nitrate-responsive root transcription factor. Further, as utility is lacking for the polynucleotides, utility is also lacking for the polynucleotides of part (g) of claim 1. Therefore the claims are seen as failing to meet the criterion of a substantial utility, and it is concluded that the specification does not disclose any utility for the claimed isolated nucleic acids.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "member" in line 1 of claims 1 and 2 render the claims, and those dependent thereon, indefinite. It is not exactly clear what is being referred to by the recitation. Nucleic acids are not commonly referred to in the art as "comprising a member." It is suggested that "member" in line 1 of claim 1 be replaced with --polynucleotide--, and in line 1 of claim 2 be replaced with --nucleic acid--.

Further regarding claim 2: there is improper antecedent basis in the claim for "a member of claim 1." Claim 1 is directed to an isolated nucleic acid, not a member. See the suggested amendment to claim 2 above.

In claim 8: there is improper antecedent basis for "root transcriptional factor polynucleotide of claim 1". Claim 1 is directed to an isolated nucleic acid, and does not refer to the polynucleotides of parts (a)-(g) as a root transcriptional factor polynucleotide.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards any isolated nucleic acid comprising a member selected from the group consisting of any polynucleotide (a) having at least 75% sequence identity to SEQ ID NO: 1, as determined by the GAP algorithm, (b) encoding SEQ ID NO: 2, (c) amplified from any nucleic acid library using primers that selectively hybridize within SEQ ID NO: 1 under any hybridization condition, (d) which selectively hybridizes to SEQ ID NO: 1 under any hybridization condition and a wash in 01.X SSC at about 60° to 65°C, (e) SEQ ID NO: 1, (f) which is complementary to (a), (b), (c), or (e), and (g) comprising at least any 50 contiguous nucleotides from a polynucleotide of (a), (b), (c), (d), (e), or (f); a recombinant expression cassette comprising said member operably linked in sense or antisense orientation to a promoter; any host cell or transgenic plant comprising said expression cassette; any transgenic seed from said plant; a method of modulating the level of nitrate-responsive root transcriptional factor in a plant, comprising introducing into a plant cell any recombinant expression cassette comprising said polynucleotide operably linked to a promoter, regenerating a plant, and inducing expression of said polynucleotide; or wherein the plant of said method is maize.

The specification indicates that a polynucleotide of the present invention is inclusive of a polynucleotide encoding the polypeptide of SEQ ID NO: 2, including the polynucleotide of SEQ

ID NO: 1 (page 21, lines 5-6). However, the specification does not describe the sequences of any polynucleotide that has at least 75% sequence identity with SEQ ID NO: 1, or which is amplified using primers that selectively hybridize with SEQ ID NO: 1, or which hybridizes to SEQ ID NO: 1, and which encodes an amino acid sequence that has the same function as SEQ ID NO: 2. The specification also does not describe the function of SEQ ID NOs: 1 and 2. The specification indicates, on page 3 for example, that the invention provides nucleic acids and proteins related to a root transcriptional factor. However, the specification does not teach that SEQ ID NO: 2 is a root transcriptional factor, that it is responsive to nitrate, or what other relationship it may have to any root transcriptional factor. While page 21 of the specification indicates that SEQ ID NO: 1 is a polynucleotide of the present invention, the specification does not describe its function. As a structure/function correlation for SEQ ID NO: 1 has not been established, the specification also does not describe any of the other claimed polynucleotides. Further, the polynucleotides having 75% sequence identity with SEQ ID NO: 1, or which are amplified from a library, or which hybridize to SEQ ID NO: 1, as claimed, can have any function, including those that are not described. Not all sequences that share at least 75% sequence identity with SEQ ID NO: 1 will encode a nitrate-responsive root transcription factor (if this is what SEQ ID NO: 1 encodes). Further, Heuer et al. (Sex. Plant Rep. 2000, Vol. 13, pages 21-27) teach a maize cDNA, ZmMADS2, encoding a MADS box transcription factor that shares 100% sequence identity with SEQ ID NO: 2 and is expressed in pollen and during pollen tube growth. While Heuer et al. also report a low level of ZmMADS2 expression in root tips, they were not able to detect ZmMADS2 transcripts in the root hair zone, which lead them to conclude that it is unlikely to regulate processes specific for root tip cell growth (pages 23-26).

Furthermore, the claims encompass polynucleotides that can be amplified using primers that can hybridize to SEQ ID NO: 1 under any stringency condition. As any two nucleic acid sequences can hybridize to each other to some extent under appropriate conditions, the claims encompass polynucleotides, of any function, that can be amplified using any set of primers. The functions of these polynucleotides are not described by the specification. The specification also provides prophetic examples of how one may construct cDNA libraries and identify genes from a computer homology search (pages 54-71). However, methods to isolate a nucleic acid sequence do not describe the sequence itself. See Fiers vs. Sugarno, 25 USPQ 2d (CAFC 1993) at 1606, which states that "[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself". Given the breadth of the claims and the lack of written description as discussed above, the specification fails to provide an adequate written description of the multitude of nucleic acid molecules encompassed by the claims.

8. Claims 1-9 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The claims are broadly drawn towards any isolated nucleic acid comprising a member selected from the group consisting of any polynucleotide (a) having at least 75% sequence identity to SEQ ID NO: 1, as determined by the GAP algorithm, (b) encoding SEQ ID NO: 2, (c) amplified from any nucleic acid library using primers that selectively hybridize within SEQ ID

NO: 1 under any hybridization condition, (d) which selectively hybridizes to SEQ ID NO: 1 under any hybridization condition and a wash in 01.X SSC at about 60° to 65°C, (e) SEQ ID NO: 1, (f) which is complementary to (a), (b), (c), or (e), and (g) comprising at least any 50 contiguous nucleotides from a polynucleotide of (a), (b), (c), (d), (e), or (f); a recombinant expression cassette comprising said member operably linked in sense or antisense orientation to a promoter; any host cell or transgenic plant comprising said expression cassette; any transgenic seed from said plant; a method of modulating the level of nitrate-responsive root transcriptional factor in a plant, comprising introducing into a plant cell any recombinant expression cassette comprising said polynucleotide operably linked to a promoter, regenerating a plant, and inducing expression of said polynucleotide; or wherein the plant of said method is maize.

As discussed above, the specification provides the nucleotide sequence of SEQ ID NO: 1, and that it encodes the amino acid sequence of SEQ ID NO: 2. However, the specification does not provide any information as to why SEQ ID NO: 2 is thought to be a nitrate responsive transcription factor, and since, as discussed above, the specification does not actually teach that SEQ ID NO: 2 is a nitrate responsive transcription factor, utility, and therefore enablement, is lacking for the claimed invention. Even if SEQ ID NO: 2 is such a root transcription factor, the specification does not teach any polynucleotides that have at least 75% sequence identity with SEQ ID NO: 1, or which are amplified using primers that hybridize to SEQ ID NO: 1, or polynucleotides that themselves hybridize to SEQ ID NO: 1 and have the same function. The specification does not teach the domains of SEQ ID NOs: 1 or 2 that are important to its functional activity. Undue experimentation would then be required by one skilled in the art to produce polynucleotides that differ in sequence from SEQ ID NO: 1 but still retains its function.

Further, the claims encompass polynucleotides that can be amplified by primers that can hybridize to SEQ ID NO: 1 under any stringency conditions. It is well established in the art that unrelated sequences can hybridize to a template sequence under low and moderate stringencies. Further, sequences that differ from SEQ ID NO: 1 by as much as 75% may not share its functional activity. As discussed above, Heuer et al. teach a cDNA encoding a maize MADS box transcription factor, ZmMADS2, that is expressed in pollen and during pollen tube growth, and has 86.7% sequence identity to SEQ ID NO: 1. ZmMADS2 shares 100% sequence identity with instant SEQ ID NO: 2.

Further, the specification does not teach any transgenic plants that transgenically express any claimed nucleic acid in sense or antisense orientation, and which increase or decrease the level of any nitrate-responsive transcription factor. The specification indicates that manipulation of a nitrate-responsive transcription factor gene such as the Arabidopsis ANR1 in agronomic crops could be of value in maximizing utilization of available nitrogen and in reducing nitrogen inputs, could have applications in soil remediation and prevention of soil erosion. However, it is inaccurate to simply assume that expression of the claimed nucleic acid sequences in transgenic plants would have such, or any, effect. Sung et al. (Plant Cell Physiol, 1997, Vol. 38, pages 4894-489), for example, teach the isolation of an apple cDNA encoding a MADS-box protein. The cDNA was expressed in transgenic plants, but the plants did not produce any non-wild type phenotype (page 488). Further, the specification does not provide any data as to why SEQ ID NO: 1 is thought to encode a nitrate-responsive transcription factor. As discussed above, ZmMADS2 shares 100% sequence identity with SEQ ID NO: 2 but is expressed in pollen and pollen tubes, and is not a nitrate-responsive root transcription factor. The amino acid sequence

of ZmMADS2 also shares 82% identity with the Arabidopsis ANR1 nitrate-responsive root transcription factor (Heuer et al., page 23), but does not have its functional activity. In light of these teachings, further guidance is required for one to confirm the function of all of the claimed isolated nucleic acids and to use them in the claimed method to modulate a nitrate-responsive root transcription factor and use the transgenic plants for the purposes taught in the specification. Furthermore, the specification does not teach how one skilled in the art would use a plant in which SEQ ID NO: 2 is not expressed or in which a nitrate-responsive transcriptional factor is not expressed. The specification teaches that the nitrate-responsive transcription factor, ANR1, is a component of a signal transduction pathway linking external nitrate to increased lateral root proliferation (paragraph bridging pages 2-3). Inhibiting ANR1 would then inhibit root growth. It is not clear how one skilled in the art would use a plant that is inhibited in root growth. See Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Furtherstill, the claims encompass any type of host cell comprising the claimed isolated nucleic acid. However, as SEQ ID NO: 1 encodes a plant protein, it is not clear how one skilled in the art would use a non-plant host cell that comprises it. See Genentech, Inc. V. Novo Nordisk, A/S, *supra*. It is suggested that host cells of claim 3 be limited to plant and bacterial cells (as bacterial cells are routinely used in the art to store nucleic acid sequences of interest, for example). Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-3 are rejected under 35 U.S.C. 102(a) as being anticipated by Heuer et al. (Sex. Plant Reprod., 2000, Vol. 13, pages 21-27).

The claims are broadly drawn towards any isolated nucleic acid comprising a member selected from the group consisting of any polynucleotide (a) having at least 75% sequence identity to SEQ ID NO: 1, as determined by the GAP algorithm, (b) encoding SEQ ID NO: 2, (c) amplified from any nucleic acid library using primers that selectively hybridize within SEQ ID NO: 1 under any hybridization condition, (d) which selectively hybridizes to SEQ ID NO: 1 under any hybridization condition and a wash in 01.X SSC at about 60° to 65°C, (e) SEQ ID NO: 1, (f) which is complementary to (a), (b), (c), or (e), and (g) comprising at least any 50 contiguous nucleotides from a polynucleotide of (a), (b), (c), (d), (e), or (f); a recombinant expression cassette comprising said member operably linked in sense or antisense orientation to a promoter; any host cell comprising said expression cassette.

Heuer et al. teach the isolation and sequence of a cDNA encoding a maize MADS box transcription factor, ZmMADS2. The nucleotide sequence, also taught in GenBank Accession

No. AF112149, has 86.7% sequence identity with instant SEQ ID NO: 1, and comprises at least 50 contiguous nucleotides of instant SEQ ID NO: 1. The ZmMADS2 cDNA sequence encodes the amino acid sequence set forth in instant SEQ ID NO: 2. The cDNA was isolated from a library that was made using the Uni-ZAP XR lambda expression vectors. It is inherent that bacterial cells were transformed with the vectors in the making of the library and isolation of ZmMADS2. The properties of being amplified from a nucleic acid library using primers that selectively hybridize to SEQ ID NO: 1 under some stringent condition, or of selectively hybridizing to SEQ ID NO: 1 under some stringent hybridization condition and a wash in 0.1X SSC at about 60° to 65°C, is inherent to the sequence.

10. Claims 1-4, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhang et al. (Science, 1998, Vol. 279, pages 407-409).

The claims are broadly drawn towards any isolated nucleic acid comprising a member selected from the group consisting of any polynucleotide (a) having at least 75% sequence identity to SEQ ID NO: 1, as determined by the GAP algorithm, (b) encoding SEQ ID NO: 2, (c) amplified from any nucleic acid library using primers that selectively hybridize within SEQ ID NO: 1 under any hybridization condition, (d) which selectively hybridizes to SEQ ID NO: 1 under any hybridization condition and a wash in 01.X SSC at about 60° to 65°C, (e) SEQ ID NO: 1, (f) which is complementary to (a), (b), (c), or (e), and (g) comprising at least any 50 contiguous nucleotides from a polynucleotide of (a), (b), (c), (d), (e), or (f); a recombinant expression cassette comprising said member operably linked in sense or antisense orientation to a promoter; any host cell or transgenic plant comprising said expression cassette; transgenic seed

of said transgenic plant; a method of modulating the level of nitrate-responsive root transcriptional factor in a plant, comprising introducing into a plant cell any recombinant expression cassette comprising said polynucleotide operably linked to a promoter, regenerating a plant, and inducing expression of said polynucleotide.

Zhang et al. teach transgenic Arabidopsis plants transformed with a construct comprising a nucleotide sequence encoding the nitrate-responsive transcriptional factor, ANR1. The ANR1 cDNA was operably linked to the CaMV 35S promoter in sense or anti-sense orientation. ANR1 RNA was repressed in the lines expressing the ANR1 cDNA in sense or antisense orientation. Seed of the transgenic plants were also collected. Zhang et al. conclude that ANR1 was down-regulated in the transgenic plant transformed with the ANR1 cDNA in sense orientation due to co-suppression. Lateral root growth was inhibited in transgenic plants treated with 1 mM or 100 μM KNO_3 (pages 407-409). Zhang et al. teach that lateral root elongation in wild type plants requires ANR1 expression. The property of being amplified from a nucleic acid library using primers which selectively hybridize under stringent hybridization conditions to loci within a polynucleotide of SEQ ID NO: 1 is inherent to the ANR1 nucleotide sequence.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. in combination with Fromm et al. (Biotechnology, 1990, Vol. 8, pages 833-839).

The claims are broadly drawn towards any isolated nucleic acid comprising a member selected from the group consisting of any polynucleotide (a) having at least 75% sequence identity to SEQ ID NO: 1, as determined by the GAP algorithm, (b) encoding SEQ ID NO: 2, (c) amplified from any nucleic acid library using primers that selectively hybridize within SEQ ID NO: 1 under any hybridization condition, (d) which selectively hybridizes to SEQ ID NO: 1 under any hybridization condition and a wash in 01.X SSC at about 60° to 65°C, (e) SEQ ID NO: 1, (f) which is complementary to (a), (b), (c), or (e), and (g) comprising at least any 50 contiguous nucleotides from a polynucleotide of (a), (b), (c), (d), (e), or (f); a recombinant expression cassette comprising said member operably linked in sense or antisense orientation to a promoter; any host cell or transgenic plant comprising said expression cassette; any transgenic seed from said plant; a method of modulating the level of nitrate-responsive root transcriptional factor in a plant, comprising introducing into a plant cell any recombinant expression cassette comprising said polynucleotide operably linked to a promoter, regenerating a plant, and inducing expression of said polynucleotide; or wherein the plant of said method is maize.

Zhang et al. teach transgenic Arabidopsis plants transformed with the ANR1 cDNA in sense or antisense orientation, as discussed above.

Zhang et al. do not teach transgenic maize plants.

Fromm et al. teach a method for producing transgenic maize plants (pages 833-836).

It would have been obvious and within the scope of one of ordinary skill in the art at the time the invention was made to overexpress the ANR1 cDNA of Zhang et al. in any plant,

including maize, using any suitable transformation method, for example the method taught by Fromm et al. One would have been motivated to overexpress the ANR1 cDNA, as Zhang et al. teach that it stimulates root elongation, which would be advantageous to a plant in, for example, nutrient uptake. One would have been motivated to overexpress ANR1 in maize, as it is an economically important crop plant.

12. Claims 1-9 are rejected. Claim 10 is withdrawn from consideration.

Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

October 15, 2002

ASHWIN D. MEHTA, PH.D
PATENT EXAMINER